REMARKS

Claims 1, 6, 12 and 14 are amended herein and claims 4, 5 and 16-17 are canceled. Support for the amendment is found, for example, at page 15, lines 11-13 and 16, page 16, lines 2, 21 and 24, and page 18, lines 11-13. No new matter is presented.

I. Information Disclosure Statement (IDS)

Applicants note that the Examiner has returned a blank PTO/SS/08 Form with the Action dated July 22, 2008 and indicates that this form was submitted with the IDS filed January 23, 2007. An IDS was submitted on October 22, 2007 citing the references that should have been listed on the PTO/SB/08 Form submitted with the IDS on January 23, 2007. Applicants respectfully request the Examiner to acknowledge and return an initialed copy of the PTO/SB/08 Form submitted with the IDS on **October 22, 2007** with the next response. A copy of the IDS filed on October 22, 2007 and the EFS Acknowledgment receipt are attached for the Examiner's convenience.

II. Response to Rejection under 35 U.S.C. § 112, first paragraph

On page 2 of the Action, claims 1-3 and 6-14 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for compounds of claim 1 where Y is alkyl or alklene, R^1 is alkyl or cyclo alkylphenyl and R^2 and R^3 are, e.g. pyran, morpholine, thiomorpholine[1] and pyridine, allegedly does not reasonably provide enablement for the broader scope of all hydrocarbons, heterocyclic groups.

[1] Applicants note that the Examiner indicates that the specification is enabling for compounds of claim 1 where R^2 and R^3 are morphine and thiomorpholine; however these compounds are not considered within the scope of the elected Group I, including compounds wherein R^2 and R^3 do not form a ring with an adjacent nitrogen.

Claim 1 is amended herein to further define the "Y" variable and the hydrocarbon and heterocyclic groups for R^1, R^2 and R^3, thereby obviating this ground for rejection. Specifically Applicants note that there are exemplary compounds in the specification which are representative of the full scope of R^1, R^2 and R^3 as recited in amended claim 1. For example, R^1 is defined as a C_{5-7} cycloalkyl group optionally fused with a benzene ring, (2) a C_{7-19} aralkyl group, (3) a 5- or 6-membered heterocyclic ring-C_{1-4} alkyl group or (4) a C_{6-14} aryloxy-C_{1-4} alkyl group, each of which may have 1 to 4 substituents selected from a halogen atom, a C_{1-4} alkyl group, a mono-, di- or tri-halogeno-C_{1-4} alkyl group and a C_{1-4} alkoxy group. Compounds 1-52, 72-75, 83-112 are within the scope of group (1); compounds 53-58, 70-71, 76-82 are within the scope of group (2); compounds 59-61, 65-69 are within the scope of group (3); and compounds 62-64 are within the scope of group (4).

Similarly, with respect to R^2 and R^3, there are exemplified compounds in the specification which include groups other than morpholine, pyran, thiomorpholine and pyridine as indicated by the Examiner. For example, there are compounds exemplified wherein R^2 is an alkyl group (see, e.g., compound nos. 70, 81-83, 86, 91, 97 and 110-111), a tetrahydropyranyl group (see, e.g., compound nos. 1, 3, 9, 14-15, 21-22, 42, 28-29, 35-36, 43-44, 51, 54, 57, 60-61, 66, 68, 71-77 and 79), a phenyl group (see, e.g., compound nos. 88, 92-96, 98-109 and 112) and a cyclohexyl group (see, e.g., 87).

In view of the above, and in view of the knowledge and skill available in the art, the direction and guidance and the exemplary compounds provided in the specification, one of ordinary skill in the art would be able to make and/or use compounds within the scope of the present claims.

Accordingly, Applicants respectfully request withdrawal of the §112, first paragraph rejection.

On page 6 of the Action, claims 8 and 9 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, allegedly does not reasonably provide enablement for making prodrugs of the claimed compounds.

Applicants submit that the rejection is improper since claim 8 was previously canceled and the phrase "prodrug thereof" was previously deleted from claim 9.

Claim 14 is amended herein by deleting the phrase "prodrug thereof", thereby obviating this ground for rejection as it might be applied to claim 14.

On page 9 of the Action, claims 9-15 are rejected under 35 U.S.C. § 112, first paragraph, because although the specification is acknowledged as enabling for vanilloid receptor agonist activity in example 51 and treatment of overactive bladder in example 51, it is argued as nonenabling for preventing overactive bladder, analgesic or vanilloid receptor agonist activity for all known hydrocarbon and/or all heterocyclic substituted compounds of formula (I).

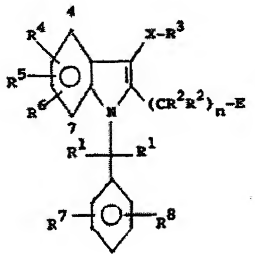
Claims 9-15 depend directly, or indirectly, from claim 1 and claim 1 is amended herein to further define formula (I). Additionally, claim 12 is amended to delete the phrase "preventing and/or". Thus, Applicants submit that the amendments to the claims obviate this ground for rejection.

Accordingly, Applicants respectfully request withdrawal of the §112, first paragraph rejections.

III. Response to Rejection under 35 U.S.C. § 103(a)

On page 12 of the Action, claims 1-13 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Gillard et al (EP 0275667) in view of Arya et al (US 3954757).

On page 4, Gillard et al (EP-A-0275667) discloses the compound of formula (I) having the following structure:



The structure of this compound is completely different from the present compounds of formula (I) having a condensed ring structure with pyridyl.

Additionally, the compounds disclosed by Gillard et al have a different activity than the compounds of the present invention. At page 3, lines 31-54, Gillard et al. discloses that the above compound has activity as leukotriene biosynthesis inhibitors and has the following effects:

> The present invention relates to compounds having activity as leukotriene biosynthesis inhibitors, to methods for their preparation, and to methods and pharmaceutical formulations for using these compounds in mammals (especially humans).
>
> Because of their activity as leukotriene biosynthesis inhibitors, the compounds of the present invention are useful as anti-asthmatic,

anti-allergic, and anti-inflammatory agents and are useful in treating allergic rhinitis and chronic bronchitis and for amelioration of skin diseases like psoriasis and atopic eczema. These compounds are also useful to inhibit the pathologic actions of leukotrienes on the cardiovascular and vascular systems for example, actions such as result in angina or endotoxin shock. The compounds of the present invention are useful in the treatment of inflammatory and allergic diseases of the eye, including allergic conjunctivitis. The compounds are also useful as cytoprotective agents and for the treatment of migraine headache.

Thus, the compounds of the present invention may also be used to treat or prevent mammalian (especially, human) disease states such as erosive gastritis; erosive esophagitis; inflammatory bowel disease; ethanol-induced hemorrhagic erosions; hepatic ischemic; noxious agent induced damage or necrosis of hepatic, pancreatic, renal, or myocardial tissue; liver parenchymal damage caused by hepatoxic agents such as $CC1_4$ and D-galactosamine; ischemic renal failure; disease-induced hepatic damage; bile salt induced pancreatic or gastric damage; trauma- or stress-induced cell damage; and glycerol-induced renal failure.

The compounds of this invention are inhibitors of the biosynthesis of 5-lipoxygenase metabolites of arachidonic acid, such as 5-HPETE, 5-HETE and the leukotrienes. Leukotrienes B_4, C_4, D_4 and E_4 are known to contribute to various disease conditions such as asthma, psoriasis, pain, ulcers and systemic anaphylaxis. Thus inhibition of the synthesis of such compounds will alleviate these and other leukotriene-related disease states.

At page 7, lines 11-24, Gillard et al further discloses:

The ability of the compounds of Formula I to inhibit biosynthesis of the leukotrienes makes them useful for inhibiting the symptoms induced by the leukotrienes in a human subject. This inhibition of the mammalian biosynthesis of leukotrienes indicates that the compounds and pharmaceutical compositions thereof are useful to treat, prevent, or ameliorate in mammals and especially in humans: 1) pulmonary conditions including diseases such as asthma, 2) allergies and allergic reactions such as allergic rhinitis, contact dermatitis, allergic conjunctivitis, and the like, 3) inflammation such as arthritis or inflammatory bowel disease, 4) pain, 5) skin conditions such as psoriasis and the like, and 6) cardiovascular conditions such as angina, endotoxin shock, and the like, and that the compounds are cytoprotective agents.

> The cytoprotective activity of a compound may be observed in both mammals and man by noting the increased resistance of the gastrointestinal mucosa to the noxious effects of strong irritants, for example, the ulcerogenic effects of aspirin or indomethacin. In addition to lessening the effect of non-steroidal anti-inflammatory drugs on the gatrointestinal tract, animal studies show that cytoprotective compounds will prevent gastric lesions induced by oral administration of strong acids, strong bases, ethanol, hypertonic saline solutions and the like.

In contrast, the present invention is based on the finding that the specific pyrrolopyridine derivative has vanilloid receptor agonist activity and is useful as a medicine such as an agent for preventing and/or treating overactive bladder or an analgesic (see the Test Examples in the specification as originally filed).

The activity of the compounds of Gillard et al as leukotriene biosynthesis inhibitors is completely different in mechanism from the vanilloid receptor agonist activity of the compounds of the present invention. Though the effect of the compounds of Gillard et al partially overlaps with the effect of the present invention because Gillard et al exemplifies pain as a subject disease for anti-inflammatory activity, the basic technical concepts of the respective inventions are completely different from each other. That is, Gillard et al is based on the inhibitory activity of leukotrienes B_4, C_4, D_4 and E_4, which are substances that cause pain, whereas the present invention is based on vanilloid receptor agonist activity.

Arya et al (US 3,954,757) describes that the disclosed condensed pyrrole mercapto compounds having a specific chemical structure show primarily vasoconstrictor activity in addition to ophthalmological and hypotensive activities, in particular, are useful as a decongestant, e.g., a nasal decongestant (see, column 3, line 63 - column 4, line 4).

Ayra et al seem to disclose compounds wherein Ar has a pyridine ring for example at

column 1, lines 25-49, but in Examples, they disclose only indol-related compounds. There is no Example of a compound having pyrrolopyridine structure in this reference.

Furthermore, Ayra et al do not describe the mechanisms of hypotensive and vasoconstrictor activities, and, there is no Test Example demonstrating the pharmacological effects. Thus, one of ordinary skill in the art would not have had a reasonable expectation of success in achieving the present invention based on the disclosure of Araya et al.

Further, since Ayra et al are different from the present invention in not only chemical structure but also in pharmacological effect and use (subject diseases), it is clear that Ayra et al does not teach or suggest the present invention. Thus, even if Gillard et al and Arya et al are combined, they do not teach or suggest the present invention. Also, since their mechanisms are different from that of the present invention, there is no motivation for combining them to arrive at the present invention. Thus, the present invention is patentable over the cited references, whether taken alone or in combination.

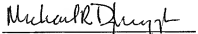
Accordingly, Applicants respectfully request withdrawal of the §103 rejection.

IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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23373
CUSTOMER NUMBER

Date: October 16, 2008

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	Docket No: Q101077
Takahiro MATSUMOTO, et al.	
Appln. No.: 10/520,784	Group Art Unit: 1625
Confirmation No.: 9335	Examiner: Raymond K. COVINGTON
Filed: January 10, 2005	

For: PYRROLOPYRIDINE DERIVATIVE AND USE THEREOF

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97 and 1.98

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, along with a copy of the corresponding Communication from a Foreign Patent Office, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003.

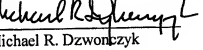
The present Information Disclosure Statement is being filed (without a Statement Under 37 C.F.R § 1.97(e)) after the later of three months from the application's filing date and the

mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier). Therefore, the statutory fee of $180.00 under 37 C.F.R. § 1.17(p) is being charged to Deposit Account No. 19 4880 via EFS Payment Screen. The USPTO is also directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account..

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,



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Date: October 22, 2007

Substitute for Form 1449 A & B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	1

Complete if Known	
Application Number	10/520,784
Confirmation Number	9335
Filing Date	January 10, 2005
First Named Inventor	Takahiro MATSUMOTO
Art Unit	1625
Examiner Name	Raymond K. COVINGTON
Attorney Docket Number	Q101077

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code[2] (if known)		
		US			
		US			
		US			
		US			
		US			
		US			
		US			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation[6]
		Country Code[3]	Number[4]	Kind Code[5] (if known)			
		EP	1 086 950	A	03-28-2001	CHUGAI SEIYAKU KABUSHIKI KAISHA	
		EP	0 275 667	A	07-27-1988	MERCK FROSST CANADA INC.	
		WO	00/75145	A	12-14-2000	ABBOTT LABORATORIES	

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation[6]
		Copy of EP Search Report dated September 1, 2006 issued in EP Application No. 03 74 1328	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or follow the hyperlink from the title of the document to the intranet. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to indicate here if English language Translation is attached.

Electronic Acknowledgement Receipt

EFS ID:	2348517
Application Number:	10520784
International Application Number:	
Confirmation Number:	9335
Title of Invention:	Pyrrolopyridine derivative and use thereof
First Named Inventor/Applicant Name:	Takahiro Matsumoto
Customer Number:	23373
Filer:	Michael R. Dzwonczyk/Lynette Mansfield
Filer Authorized By:	Michael R. Dzwonczyk
Attorney Docket Number:	Q101077
Receipt Date:	22-OCT-2007
Filing Date:	10-JAN-2005
Time Stamp:	10:40:26
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	$180
RAM confirmation Number	5117
Deposit Account	194880
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 and 1.17	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed	Q101077IDS.pdf	129804 858b28ffd1677216ce16acaf901aad7b116b72a	no	3
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
2	NPL Documents	SearchReport.pdf	114808 a247c8ca4629bb65b3a1c6d2fd5c4b0fc565ae	no	3
Warnings:					
Information:					
3	Foreign Reference	EP0275667.pdf	2352333 1ebf3525c0d31c03b1140d3a5f57c6d7d29d69d0	no	78
Warnings:					
Information:					
4	Foreign Reference	EP1086950A1.pdf	385908 6915fa02f5580c40a3202033f865f8ce01ab902	no	64
Warnings:					
Information:					
5	Foreign Reference	WO0075145.pdf	12628376 550f269e19e34a6d3d7c9ef2e7435e0fbe5271c	no	320
Warnings:					
Information:					
6	Fee Worksheet (PTO-06)	fee-info.pdf	8200 5542beb61877e606277caea9116f603a8cd243c7	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	15619429		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.